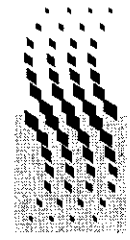


Vascular
SOLUTIONS

JAN - 5 2007

510(k) SUMMARY

510(k) Number: K062627

Date Prepared September 1, 2006

Submitter Information

Submitter's Name/ Address:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369
Establishment Registration	2134812
Contact Person:	Patrice Stromberg Sr. Regulatory Affairs Associate (763) 656-4243 telephone (763) 656-4200 fax pstromberg@vascularsolutions.com

Device Information

Trade Name:	InnerChange™ Micro-Introducer Catheter
Common Name:	Diagnostic Intravascular Catheter
Classification Name:	Diagnostic Intravascular Catheter
Product Code:	DQO
Regulation:	Class II, 21 CFR 870.1200

Predicate Device(s)

- Merit Medical Angiographic Catheter (K000659)
- Galt Micro-Introducer Kits (K000737)
- Vascular Solutions Langston Dual Lumen Pressure Monitoring Catheter (K061565)

Device Description

The InnerChange Micro-Introducer Catheter combines the function of a micro introducer and angiographic catheter. Each InnerChange Micro-Introducer

Catheter consists of the following components: Stainless Steel percutaneous entry needle, Nitinol Guidewire with Stainless Steel tip, dilator, and catheter with selected tip shape and high pressure stopcock. The dilator functions to straighten the catheter tip during vascular access. When the dilator is removed, the catheter tip returns to the preformed configuration. The Inner-Change Micro-Introducer Catheter will be available in 4F and 5F sizes with various tip curve configurations and lengths ranging from 45 to 125cm.

Intended Use/Indications for Use

The InnerChange Micro-Introducer Catheter is intended for use in accessing the vascular system through a small gauge needle stick and for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

Summary of Non-Clinical Testing

Performance Testing: Device Verification Testing was performed to support the equivalency of the InnerChange Micro-Introducer Catheter to the predicate devices. Testing included mechanical, functional, shelf life and packaging testing. DVT testing included Catheter Curve Retention, Catheter – Dilator Passage, Taper & Length, Catheter Tortuosity, Catheter Air Leakage into Hub Assembly during Aspiration, Catheter Dynamic Fluid Testing, Catheter Static Pressure Testing, Catheter Flow Rate, Bond Strength: Catheter, Dilator and Guidewire. The InnerChange Micro-Introducer Catheter met all specified design and performance requirements.

Biocompatibility. Biocompatibility testing in accordance with ISO 10993, "Biological Evaluation of Medical Devices" was provided. The material used in the InnerChange Micro-Introducer Catheter has been demonstrated to be biocompatible.

Summary of Clinical Testing

No clinical evaluations of this product have been conducted.

Statement of Equivalence

The InnerChange Micro-Introducer Catheter is similar in intended use and function to the Merit Medical Angiographic Catheters, Galt Micro-Introducer Kits, and the Vascular Solutions Langston Dual Lumen Pressure Monitoring Catheter.

Conclusion

Through the data and information presented, Vascular Solutions considers the InnerChange Micro-Introducer Catheter to be substantially equivalent to the Merit Medical Angiographic Catheters, Galt Micro-Introducer Kits, and the Vascular Solutions Langston Dual Lumen Pressure Monitoring Catheter. The testing performed confirms that the InnerChange Micro-Introducer Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2007

Vascular Solutions, Inc.
c/o Ms. Patrice Stromberg
Sr. Regulatory Affairs Associate
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K062627/S1
Trade/Device Name: InnerChange™ Micro-Introducer Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: catheter, intravascular, diagnostic
Regulatory Class: II
Product Code: DQO
Dated: November 22, 2006
Received: November 24, 206

Dear Ms. Stromberg:

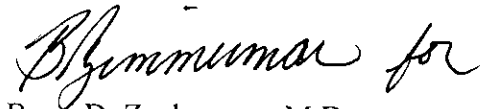
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K062627

Device Name: InnerChange™ Micro-Introducer Catheter

Indications for Use:
The InnerChange™ micro-introducer catheter is intended for use in accessing the vascular system through a small gauge needle stick and for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

Prescription Use ___X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062627